

Amendments to the Drawings:

The attached sheet of drawings includes changes to FIG. 1. This sheet, which includes FIGS. 1 and 2, replaces the original sheet depicting FIGS. 1 and 2.

Attachment: Replacement sheet

REMARKS/ARGUMENTS

The claims are 3-11. Claims 1-2 have been canceled in favor of new claim 11 to better define the invention. Accordingly, claims 3 and 6, which previously depended on claim 1 have been amended to depend on new claim 11. These claims and claims 4, 5, 7 and 8 have also been amended to improve their form. In amended FIG. 1, the pad 4 has been shown with a convex surface as is shown, for example, in FIG. 5, and the reference numeral 6 has been added to identify a closing element, as in FIG. 2. The specification has also been amended to correct certain idiomatic and grammatical errors believed to have resulted from the translation. Support may be found, inter alia, in the disclosure in the paragraph bridging pages 1-2, the paragraph bridging pages 3-4, the paragraph bridging pages 6-7, FIGS. 3, 4, 5 and 6 and original claims 1 and 2. Reconsideration is expressly requested.

Applicants wish to thank the Examiner for the courtesy of an interview on May 5, 2005, the substance of which is recorded in the Examiner's Interview Summary Record and herein. Prior to the filing of the Request for Continued Examination (RCE), claim 4 was objected to on formal grounds as lacking antecedent basis for "closing elements", claims 1-2 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Epler et al U.S. Patent No. 5,135,473*, and claims 3-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Epler et al* in view of *Wehr U.S. Patent No. 5,503,622*, or *Morris et al. U.S. Patent*

No. 5,501,659 or DE 3300111 alone (claims 3-7) or further in view of *Mason et al.* U.S. Patent No. 4,938,777 (claims 8-10). Claims 6-10 were also been rejected under 35 U.S.C. § 103 as being unpatentable over *Wehr* in view of *Epler et al.* alone (claims 6-7) or further in view of *Mason et al.* (claims 8-10).

In response to the Examiner's rejection to claim 4 as lacking proper antecedent basis for "closing elements", it is respectfully submitted that the recitation of closing elements in claim 4 finds proper antecedent basis in claim 3 as claim 4 is dependent on claim 3, which recites that the functional component comprises closing elements. Accordingly, it is respectfully requested that the objection to claim 4 as lacking antecedent basis be withdrawn.

With respect to the prior art rejections, essentially the Examiner's position was that *Epler et al.* discloses the orthosis cuff recited in the claims, except for features of the dependent claims, which were said to be taught by the secondary references. With respect to claims 6-10, the Examiner alternatively relied on *Wehr* as a primary reference, except for features recited in these claims, which were said to be taught by either *Epler et al.* or *Mason et al.* The Examiner also requested an English language translation of DE 3300111 be submitted.

At the interview, the prior art rejection of the claims was discussed, and Dr. Oswald Wolff, one of the inventors, showed a prototype of the cuff and discussed this operation and effect. In addition, the Examiner was advised of the issuance of Applicants' German Patent No. DE 197 48 836 C2. The Examiner indicated that FIG. 1 should be amended to show the pad with a convex surface. The Examiner also suggested defining the pad more in terms of structure and location which would likely overcome the *Epler et al.* reference, subject to further consideration and search.

In response, Applicants have amended FIG. 1 to show the pad with a convex surface, have canceled claims 1 and 2 in favor of new main claim 11, which recites, inter alia, that the cuff includes (a) a functional component adapted to the outer contour of a wearer's lower leg and surrounding the lower leg near the upper ankle joint so that when the cuff is worn, the mobility of the wearer's upper ankle joint and the Achilles tendon is not restricted, and (b) a pad having a convex surface arranged on an inside portion of the functional component so that when the cuff is worn, the convex surface rests anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized. Support for the pad having a convex surface is shown, inter alia, in FIGS. 5 and 6 and also FIGS. 3 and 4 and the discussion in the paragraph on pages 6-7 of the disclosure

which recites that the pad rests externally against the fibula and tibia in the region of the tibiofibular syndesmosis as indicated in FIG. 4 by arrow 5. It is respectfully submitted that one skilled in the art upon reading Applicants' disclosure would understand that pad 4 would have a convex surface in order to achieve an external stabilization of the tibiofibular syndesmosis as discussed, for example, at page 2, first full paragraph of the disclosure. Moreover, it is respectfully submitted that the claims, as amended, sufficiently define over the prior art for the following reasons.

As set forth in new claim 11, Applicants' invention provides an orthosis cuff for the treatment or therapy of Ledderhose's disease or hypermobile foot joints. As described in the specification, Ledderhoses's disease is a particularly painful contraction of the plantar fascia of the foot in which small nodules form on the sole of the foot that makes it almost impossible to stand on the foot without pain. Surprisingly, Applicants' orthosis cuff relieves this pain on the bottom of the foot by stabilizing the tibiofibular syndesmosis above the ankle. In addition, Applicants' orthosis cuff has been found to be effective in preventing sprains occurring as a result of hypermobile foot joints. Hypermobile foot joints is a condition that occurs with relatively young people where the person can, in effect, step on his or her own foot when walking which can result in the person spraining his or her own ankle. With the use of

Applicants' orthosis cuff, spraining on the ankle is much less likely to occur.

As shown in FIG. 4 of the drawings, Applicants' cuff 1 includes a functional component 2 (or 7 as shown in FIGS. 5 and 6) made of stiff material and includes a pad 4 arranged on the inside of the functional component. As shown in FIG. 4, when worn, the functional component encloses the lower leg near the upper ankle joint and fits the outer contour of the lower leg but leaves the upper ankle joint unrestricted. With this arrangement, the convex surface of the pad rests anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis so that the tibiofibular syndesmosis is stabilized yet the mobility of the upper ankle joint and the Achilles tendon is unrestricted. This selective stabilization above the ankle alleviates pain at the sole of the foot and makes spraining of the ankle less likely from hypermobile foot joints.

Applicants have a theory as to how their orthosis cuff operates, which the Examiner may find helpful to consider. The tibiofibular syndesmosis is like a band that holds the tibia and the fibula inside it. Referring to FIG. 4, the tibia is the bone on the right hand side and the fibula is the bone on the left hand side. (For a person's other foot, the arrangement is reversed.) The tibia is stationary but the fibula moves within

the tibiofibular syndesmosis. What Applicants' orthosis cuff does is press on the fibula to reduce the motion of the fibula. This reduction in motion of the fibula allows the tendons which are unrestricted to work better to perform their functions. The tendons near the ankle are linked to other tendons which are, in turn, ultimately linked to the tendons in the sole of the foot. Surprisingly, the selective stabilization of the tibiofibular syndesmosis, while leaving the Achilles tendon and upper ankle joint mobile, alleviates pain in the sole of the foot and also had the effect of reducing the likelihood of sprains from hypermobile joints.

None of the prior art shows an orthosis cuff that achieves selective stabilization of the tibiofibular syndesmosis while not restricting mobility of the upper ankle joint and the Achilles tendon.

Epler et al. shows an Achilles tendon wrap or brace with a compressive pad for applying force above and perpendicular to the Achilles tendon. See title and abstract of *Epler et al.* *Epler et al.*'s pad provides compression to the Achilles tendon. See Abstract, column 2, lines 16-17 and 61-62 and column 4, lines 15-16. There is no disclosure or suggestion of a pad that rests anterolaterally on the wearer's leg while leaving unrestricted the mobility of the wearer's upper ankle joint and Achilles tendon. Moreover, *Epler et al.*'s pads cannot provide

stabilization of the tibiofibular syndesmosis, whether worn as intended or in some other way. When worn as intended, the pad presses posteriorly on the Achilles tendon. In addition, one could not dispose *Epler et al.*'s pad in the region of the tibiofibular syndesmosis, as suggested by the Examiner. First, there is no reason to do so and is contrary to the purpose of *Epler et al.*, which teaches applying force to the Achilles tendon. Second, *Epler et al.*'s tendon support is matched very closely to the anatomy. See Abstract lines 3 and 9-13, column 2, lines 26-27, 31-32 and 63, and column 3, lines 24 and 41-44 of *Epler et al.* Thus, one would be unable to put the pad of *Epler et al.* near the tibiofibular syndesmosis because to do so would cause *Epler et al.*'s pad to have little, if any effect, either for supporting the Achilles tendon as is *Epler et al.*'s purpose or for stabilizing the tibiofibular syndesmosis as Applicants' cuff is designed to do.

Wehr discloses a bandage that is wrapped around the upper ankle joint and is supposed to stabilize it. *Wehr* provides encompassing pressure around the ankle to limit the eversion and inversion of the ankle and the foot. See column 1, lines 10-16 and 60-65, column 2, lines 3-8, 52-54 and 60-64, and column 3, lines 7-12 and 24-26 of *Wehr*. In contrast, Applicants' orthosis cuff is intended to be disposed near the upper ankle joint and leave it free. Applicants' objective is entirely different from

Wehr, which naturally also affects the configuration of the bandage. Accordingly, *Wehr* cannot anticipate nor render obvious the subject matter of Applicants' orthosis cuff as recited in new claim 11.

The defects and deficiencies of *Epler et al.* or *Wehr* are nowhere remedied by any of the secondary references to *Morris, DE 3300111 to Thomas* or *Mason et al.* *Morris et al.* discloses an ankle brace that is intended to stabilize the upper ankle joint, which it therefore **does not** leave free or unrestricted.

DE 3300111 to Thomas discloses a brace, which in the applied condition grips around a large part of the back of the foot as well as of the adjoining upper ankle joint, and for this reason alone is entirely noncompatible with Applicants' orthotic cuff, as recited in claim 11, in which the functional component surrounds the lower leg near the upper ankle joint so that when the cuff is worn the mobility of the wearer's upper ankle joint and the Achilles tendon is not restricted.

Similarly, *Mason et al.* ankle orthosis cuff attempts to prevent the eversion and inversion of the foot and therefore restricts the mobility of the wearer's upper ankle joint. See column 2, line 62. Unlike Applicants' orthosis cuff, moreover, *Mason et al.*'s ankle orthosis teaches that it is necessary to have a rib 10 composed of a single vertical riser 12 and a lower cup shoe or section to achieve its objectives. See also FIGS. 1,

3-6 and 9. These structures restrict movement of the wearer's ankle and leg. For example, a person wearing *Mason et al.*'s cuff cannot stand on the balls of his feet because of the restriction at the back of the leg, ankle and foot. In contrast, Applicants' orthosis cuff has no such rib or other structure restricting movement. In Applicants' cuff, mobility of the ankle is entirely unrestricted. Moreover, Applicants' cuff contains a pad having a convex surface resting anterolaterally on the wearer's leg against the fibula and tibia in the region of the wearer's tibiofibular syndesmosis, which stabilizes the tibiofibular syndesmosis, which is nowhere disclosed or suggested by *Mason et al.*

Accordingly, it is respectfully submitted that new claim 11 and claims 3-10 dependent thereon are patentable over the cited references.

In summary, claims 1 and 2 have been canceled, claims 3-8 have been amended and new claim 11 has been added. The specification and FIG. 1 have also been amended. In view of the foregoing, it is respectfully requested that the claims be allowed and that this application be passed to issue.

Applicants also submit herewith a Supplemental Information Disclosure Statement citing the references cited in Applicants' German Patent No. DE 197 48 836 C2.

Respectfully submitted,
OSWALD WOLFF ET AL. (PCT) (RCE)

COLLARD & ROE, P.C.
1077 Northern Boulevard
Roslyn, New York 11576
(516) 365-9802


Allison C. Collard, Reg.No.22,532
Frederick J. Dorchak, Reg.No.29,298
Attorneys for Applicants

FJD:jc

Enclosure: Appendix - One Replacement Sheet
Supplemental Information Disclosure Statement
Copy of 2-month Extension of Time

EXPRESS MAIL NO. EV 621 914 005 US
Date of Deposit: May 26, 2005

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10, on the date indicated above, and is addressed to Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Melissa Konko